REMARKS

Reconsideration and allowance of the above-referenced application are respectfully requested.

Claims 1-6, 39 and 41-47 are pending. Claims 7 and 40 have been cancelled, and claims 5, 41, 42, 46 and 47 have been amended.

Additionally, the Examiner is requested to note that U.S. patent application Ser. No. 09/215,818 has been allowed but has not yet issued. Thus, the specification has been amended to reflect the proper serial number as well as the status of allowance. Furthermore, the specification has been amended to reflect the fact that U.S. patent application Ser. No. 08/912,276 has issued as U.S. Patent No. 6,183,952 on February 6, 2001.

Also, the Examiner has objected to claim 5 due to the lack of sequence identification number. Although unnecessary due to dependency, the sequence number was added to claim 5 for clarification.

Furthermore, the Examiner has objected to claims 7 and 40 arguing an improper dependent from for failing to further limit the subject matter of the previous claim. In response to the objection, claims 7 and 40 have been cancelled.

Additionally, the Examiner has objected to the drawings for reasons cited on form PTO 948. Applicant respectfully requests that this objection be held in abeyance until allowable subject matter is found.

1. Rejection of Claims 7, 40-42, 46 and 47 under 35 U.S.C. § 112, first paragraph.

The Examiner has rejected claims 7, 40-42 and 47 under Section 112, first paragraph.

The Examiner's Position

The Examiner contends that the specification, while being enabling for the polypeptides having the amino acid sequences of SEQ ID NO: 2, SEQ ID NO: 3 and SEQ ID NO: 10, does not reasonably provide enablement for variants that have at least 20% sequence identity. The Examiner claims that there is no guidance as to how to make these variants and how to determine their specific functions. Likewise, the Examiner is concerned with the possibility that the "20% identity" may encompass a vast collection of polypeptides, and provides inadequate instruction to allow one skilled in the art to make

and use said naturally occurring polypeptide with a reasonable expectation of success and without undue experimentation.

The Examiner also contends that the specification, while enabling for a multimeric polypeptide (MPA) consisting of EU250 (SEQ ID NO:3), BU101 (SEQ ID NO:2) and TU104 (SEQ ID NO:10), does not reasonably provide enablement for a MPA consisting of arbitrary fragments of the said sequences. In particular, the Examiner notes that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicants' Position

Applicants respectfully submit the above amendments to the claims adequately address the Examiner's concerns. Thus, it is respectfully requested that the Examiner withdraw this rejection accordingly.

The Examiner also contends that the claimed fragments in claims 7 and 40-47 are arbitrary fragments of the mentioned sequences and that one of ordinary skilled in the art would not be able to select all the possible fragment combinations with a reasonable expectation of success and without undue experimentation.

Applicants again respectfully submit that the above amendments adequately address the Examiner's concerns. Thus, the rejection should be withdrawn accordingly.

2. Rejection of Claims 1-7 and 39-47 under 35 U.S.C. § 112, second paragraph.

The Examiner has rejected claims 1-7 and 39-47 under Section 112, second paragraph.

The Examiner's Position

Examiner is concerned with the vagueness and indefiniteness of the abbreviations "EU250" and "TU104" used for the polypeptides.

The Applicants' Position

Applicants respectfully submit that the terms "EU250" and "TU104" were designed by the present inventors and are amino acid seqences represented by SEQ ID NO:3 and SEQ ID NO:10, respectively. Furthermore, the claims recite these sequence identifiers. Also, it should be noted that the characteristics of the polypeptides are fully disclosed in the specification, and the claims must be read in light of the specification.

Finally, it must be noted that Applicants are allowed to draft their own terms where appropriate. Thus, in view of the above, it is submitted that the rejection has been overcome and should be withdrawn.

3. Rejection of Claims 1-7 and 39-47 under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1-7 and 39-47 under Section 103 as being obvious over U.S. Patent Number 6,066,724.

The Examiner's Position

The Examiner contends that, due to the broadness of claims 7 and 40, U.S. Patent 6,066,724 teaches polypeptides comprising variants or derivative of Applicants' sequences identified as SEQ NO: 3, 2, and 10 which intrinsically may or may not contain unknown polypeptides. Further, the Examiner contends that SEQ ID NO:4 and 2 of the patent are the same as Applicants' claimed SEQ ID NO:3 and 2, respectively.

Additionally, the Examiner contends that it would have been prima facie obvious to the skilled artisan at the time the invention was made to combine the polypeptides, variants, fragments and other compounds of the patent.

The Applicants' Position

The Applicants respectfully traverse the rejection of claims 1-7 and 39-47 under Section 112, as being obvious over U.S. Patent No. 6,066,724 (Ni et al.).

Initially, it is submitted that claims 7 and 40 have been cancelled, thereby rendering the rejection, as applied to these two claims, moot.

Additionally, it is submitted that Ni et al.teach hESF I, II and III polypeptides and uses thereof. There is absolutely no teaching or suggestion in the patent, however, as to which of the polypeptides should be used in combination. In particular, there is no teaching or suggestion that the sequence corresponding to EU250 of the present invention must be present in a multimeric polypeptide antigen or complex (see claim 1 of the present application). One of ordinary skill in the art certainly would not have been motivated to have used this particular sequence (i.e., EU 250), in combination with BU101 and/or TU104 (and possibly at least one other polypeptide) based upon the teachings and suggestions of Ni et al., nor would one have been motivated to have developed an antibody against the combination or complex.

Furthermore, it is submitted that the TU104 sequence of the present invention is only 92.4% similar to the sequence of Ni et al. Thus, different sequences are being

compared, thereby also supporting the concept that the presently claimed invention is not obvious over Ni et al.

In view of the above, it is submitted that the rejection of claims 1-7 and 39-47 under Section 103(a) as being obvious over U.S. Patent No. 6,066,724 has been overcome and should be withdrawn accordingly.

In conclusion, it is believed that the subject application is in condition for allowance and Notice to that effect is respectfully requested.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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Version with Markings to Show Changes Made

IN THE SPECIFICATION:

Page 1, lines 7-16:

This application is a continuation-in-part of pending U.S. patent application Serial No. 09/467,602 filed on December 20, 1999, which is a continuation-in-part of [pending] allowed U.S. patent application Serial No. [08/215,818] 09/215,818 filed on December 18, 1998, which is a continuation-in-part of 1) [pending U.S. patent application Serial No. 08/912,149 filed on August 17, 1997] U.S. Patent No. 6,183,952, issued on February 6, 2001, which is a continuation-in-part of U.S. patent application Serial No.08/697,105, filed on August 19, 1996, now abandoned, as well as 2) a continuation-in-part of pending U.S. patent application Serial No. 08/912,149, filed on August 15, 1997, which is a continuation-in-part of U.S. application Serial No. 08/697,106, filed on August 19, 1996, now abandoned, from which priority is claimed pursuant to 35 U.S.C. § 120 and which are all incorporated herein by reference in their entity.

IN THE CLAIMS:

5. (Amended) The antigen of claims 1 and 2 wherein said at least one BU101 polypeptide (SEQUENCE ID NO:2) contains a polymorphism at amino acid position number 53 selected from the group consisting of proline and leucine.

41. (Amended) The composition of matter of [claims] claim 39 [or 40] wherein composition further comprises at least one antibody, bound to said multimeric polypeptide antigen, wherein said antibody is specific to at least one polypeptide selected from the group consisting of a EU250 polypeptide, a BU101 polypeptide, a TU104 polypeptide, a polypeptide [having at least 20% identity with] having an amino acid sequence selected from the group consisting of [SEQ] SEQUENCE ID NO:3, [SEQ] SEQUENCE ID NO:2[,] and [SEQ] SEQUENCE ID NO:10[, and fragments thereof].

42. (Amended) The composition of matter of claim 41 wherein two antibodies are present and each binds to a separate polypeptide having an amino acid sequence [having at least 20% identity with an amino acid sequence] selected from the group consisting of [SEQ] SEQUENCE ID NO:3, [SEQ] SEQUENCE ID NO:2[,] and [SEQ] SEQUENCE ID NO:10[, and fragments thereof].

43. (Amended) The composition of matter of claim 42 wherein each of said two antibodies binds to a EU250 polypeptide [or a fragment thereof].

44. (Amended) The composition of matter of claim 42 wherein each of said two antibodies binds to a polypeptide selected from the group consisting of a BU101 polypeptide[,] and a TU104 polypeptide[, and fragments thereof].

45. (Amended) The composition of matter of claim 42 wherein one of said two antibodies binds to a EU250 polypeptide [or a fragment thereof] and the other of said two antibodies binds to a polypeptide selected from the group consisting of a BU101 polypeptide[,] and a TU104 polypeptide[, and fragments thereof].

46. (Amended) The composition of matter of claim 42 wherein one of said two antibodies binds to a EU250 polypeptide [or fragment thereof] and the other of said two antibodies binds to a polypeptide having an amino acid sequence [having at least 20% identity with an amino acid sequence] selected from the group consisting of [SEQ] SEQUENCE ID NO:3, [SEQ] SEQUENCE ID NO:2[,] and [SEQ] SEQUENCE ID NO:10[, and fragments thereof].

47. (Amended) The composition of matter of claim 42 wherein one of said antibodies binds to a polypeptide selected from the group consisting of a BU101 polypeptide, a TU104 polypeptide, [and fragments thereof,] and the other of said two antibodies binds to a polypeptide having an amino acid sequence having [at least 20% identity with] an amino acid sequence selected from the group consisting of [SEQ] SEQUENCE ID NO: 3, [SEQ] SEQUENCE ID NO:2[,] and [SEQ] SEQUENCE ID NO:10[, and fragments thereof].